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Tebuconazole Final Work Plan

Registration Review
Case Number 7004

June 2016

Approved by:

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INTRODUCTION

This is the Environmental Protection Agency's (EPA or the Agency) Final Work Plan (FWP) for the registration review of tebuconazole. This work plan addresses public comments received concerning the Preliminary Work Plan (PWP), which was posted in the tebuconazole registration review docket (EPA-HQ-OPP-2015-0378). Tebuconazole is a fungicide registered as a conventional pesticide with agricultural and non-agricultural use patterns, and as an antimicrobial pesticide with wood preservative, materials preservative, and metalworking fluid uses.

The Agency is implementing the registration review program pursuant to Section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. Changes in science, public policy, and pesticide use practices occur over time. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard. The public phase of registration review begins when the initial docket is opened for each case. Information on this program is provided on the Agency's website.[1]

The FWP begins with any updates since the PWP was issued. Next is a summary of substantive comments received during the public comment period for the PWP concerning anticipated data needs, expected risk assessments, or the estimated timeline identified in the PWP, and a summary of the Agency's responses to those comments. This section is followed by registration review planned data needs, risk assessments expected to be conducted, and the projected registration review timeline for tebuconazole. Lastly, there is a discussion of next steps.

UPDATES SINCE THE PWP WAS ISSUED

There are no additional updates on tebuconazole since the PWP.

SUMMARY OF COMMENTS AND AGENCY RESPONSES

During the 60-day public comment period on the Tebuconazole Preliminary Work Plan, which opened on January 11, 2016 and closed on March 11, 2016, the Agency received comments from 6 stakeholders. Comments were submitted by the Center for Biological Diversity, Bayer CropScience, the U.S. Department of Agriculture, the Northwest Horticultural Council, the Physicians Committee for Responsible Medicine, and the FIFRA Endangered Species Task Force. The comments do not address the timeline described in the PWP, but some do address the planned ecological data requirements. In the PWP, EPA also solicited comments on the specific topics of environmental justice, water quality concerns, and trade irritants, but no comments or information were received on those issues.

This section does not capture every comment made about the PWP nor all of the Agency's responses. Summarized public comments and Agency responses related to the anticipated ecological risk assessment or data needs are in the *EFED Response to Comments Submitted on*

[1] http://www2.epa.gov/pesticide-reevaluation

the Preliminary Problem Formulation for Ecological Risk and Drinking Water Assessments for the Registration Review of Tebuconazole, available in the tebuconazole docket. Summarized below are public comments of a broader regulatory nature. Public comments in their entirety are located in the docket, EPA-HQ-OPP-2015-0378.

Comments submitted by the Northwest Horticultural Council in EPA-HQ-OPP-2015-0378-0011

Comment: *The NWHC commented on the importance of tebuconazole for control of Blossom Blight and fruit Brown Rot (Monolinia spp.), Cherry Leaf Spot, and Powdery Mildew in stonefruit, as well as for the control of Powdery Mildew, Cedar Apple Rust, and Scab on apple and pear crops.*

Comments submitted by the Physicians Committee for Responsible Medicine in EPA-HQ-OPP-2015-0378-0012

Comment: *PCRM requested that the Agency consider selecting representative conazoles with which to generate test data, thereby reducing the number of overall tests conducted.*

EPA Response: The Agency thanks PCRM for its comment but does not believe such an approach would be appropriate. Based on the limited dataset for the conazoles, results for acute oral toxicity testing with the bobwhite quail vary widely despite similar chemical structures. Therefore, selection of appropriate chemical(s) to represent the conazoles group as surrogates is difficult and the test is unlikely to capture the broad range of results possible for the conazoles group. Additionally, the known challenges in conducting acute oral testing with passerines (i.e., regurgitation), increase the uncertainty in results and decrease the confidence in successfully implementing a bridging approach to use data from one chemical to another.

Response: The Agency appreciates the information provided by the NWHC and will take it under consideration.

Comments submitted by the Center for Biological Diversity in EPA-HQ-OPP-2015-0378-0013

Comment: *The Center for Biological Diversity's (CBD) comments focus on the EPA's duty to consult with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (the Services) on the registration review of tebuconazole in accordance with the Endangered Species Act (ESA). The CBD comments mention various aspects of the risk assessment process, including use of the best available data to develop endangered species risk assessments, and evaluation of effects on endangered and threatened species and their designated critical habitat. CBD also expresses concern regarding the rigor of the Agency's preliminary determinations regarding the effects of tebuconazole on endangered and threatened (listed) species and their designated critical habitat.*

Response: EPA has reviewed the comments from CBD on the registration review docket opening for tebuconazole and plans to address many of the concerns raised by CBD as part of the

implementation plan for assessing the risks of pesticides to listed species based on the recommendations of the April 2013 National Academy of Sciences (NAS) report. EPA will address concerns specific to tebuconazole in connection with the development of its final registration review decision for tebuconazole.

In November 2013, the EPA, along with the Services and the USDA, released a summary of their joint Interim Approaches for assessing risks to listed species from pesticides. The Interim Approaches were developed jointly by the agencies in response to the NAS report recommendations and reflect a common approach to risk assessment shared by the agencies as a way of addressing scientific differences between the EPA and the Services. The NAS report[2] outlines recommendations on specific scientific and technical issues related to the development of pesticide risk assessments that EPA and the Services must conduct in connection with their obligations under the ESA and FIFRA.

The joint Interim Approaches were released prior to a stakeholder workshop held on November 15, 2013. In addition, the EPA presented the joint Interim Approaches at the December 2013 Pesticide Program Dialogue Committee (PPDC) and State-FIFRA Issues Research and Evaluation Group (SFIREG) meetings. The agencies also held stakeholder workshops in April and October 2014, and in April 2015, allowing additional opportunities for stakeholders to comment on the Interim Approaches. Additional workshops are planned to enhance stakeholder involvement. As part of a phased, iterative process for developing the Interim Approaches, the agencies will also consider public comments on the Interim Approaches in connection with the development of upcoming registration review decisions. The details of the joint Interim Approaches are contained in the white paper "Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report,"[3] dated November 1, 2013.

Given that the agencies are continuing to develop and work toward implementation of the Interim Approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, the ecological problem formulation supporting this FWP for tebuconazole does not describe the specific ESA analysis, including effects determinations for specific listed species or designated critical habitat, to be conducted during registration review. In the ecological problem formulation document for tebuconazole, EPA described the screening-level risk assessment to determine the potential effects of tebuconazole on all taxa of non-target wildlife and plants, which will assume that listed species and their designated critical habitats may be present in the vicinity of the application of tebuconazole. This screening-level assessment will allow EPA to focus its future evaluations on the types of species where the potential for effects exists once the scientific methods being developed by the agencies have been fully vetted. While the agencies continue to develop a common method for ESA analysis, the planned screening-level risk assessment for the registration review of tebuconazole will describe the level of ESA analysis completed for this particular registration review case. Once the agencies have fully developed and implemented the scientific methods necessary to complete

[2] http://www.nap.edu/catalog.php?record_id=18344
[3] http://www.epa.gov/espp/2013/nas.html

risk assessments for listed species and their designated critical habitats, these methods will be applied to subsequent analyses for tebuconazole as part of completing this registration review.

Comments submitted by the FIFRA Endangered Species Task Force (FESTF) in EPA-HQ-OPP-2015-0378-0014

Comment: *The FIFRA Endangered Species Task Force (FESTF) submitted a comment informing the Agency that tebuconazole's technical registrants are FESTF members and are entitled to rely on FESTF data.*

EPA Response: The Agency thanks FESTF for its comment and will take this under consideration.

Comments submitted by the Office of Pest Management Policy, US Department of Agriculture in EPA-HQ-OPP-2015-0378-0015

Comment: *USDA/OPMP commented on the importance of triazoles, like tebuconazole, as one of the few fungicide groups that provide protective, curative and eradicative activities when disease symptoms are visible. They also commented on the impact of increased regulation to growers and provided benefits information and usage data.*

EPA Response: The Agency thanks USDA/OPMP for its comment and will take them under consideration.

PLANNED DATA NEEDS

Table 1 below summarizes the planned data needs for tebuconazole based on the *Registration Review – Preliminary Problem Formulation for Ecological Risk and Drinking Water Assessments for Tebuconazole* and *Tebuconazole. Human Health Scoping Document in Support of Registration Review,* and *EFED Response to Comments Submitted on the Preliminary Problem Formulation for Ecological Risk and Drinking Water Assessments for the Registration Review of Tebuconazole*. The planned data needs have not changed from what was included in the PWP.

Table 1: Planned Data Needs for the Tebuconazole Registration Review

Guideline Number[4]	Study Title[4]	Test Material	Estimated Timeframe (Months from receipt of DCI)
Planned Data Needs for Tebuconazole – Conventional and Antimicrobial Uses			

[4] On June 27, 2012, EPA announced certain revisions in harmonized guideline series 850 – Ecological Effects Tests – including renumbering and other designations or changes for some guideline studies. See "Final Test Guidelines; OCSPP 850 Series; Notice of Availability" 77 FR 38282, June 27, 2012. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0154-0028

Table 1: Planned Data Needs for the Tebuconazole Registration Review			
Guideline Number[4]	**Study Title[4]**	**Test Material**	**Estimated Timeframe (Months from receipt of DCI)**
850.4500	Algal toxicity study[5, 6]	TGAI	12
850.4550	Cyanobacteria toxicity[6]	TGAI	12
Non-guideline	Freshwater chronic sediment toxicity[7]	TGAI	24
Non-guideline	Estuarine/marine chronic sediment toxicity[8]	TGAI	24
Planned Data Needs for Tebuconazole – Conventional Uses Only			
850.2100	Avian oral toxicity (passerine species)	TGAI	12
850.3020	Adult honey bee acute contact toxicity	TGAI	12
850.3030	Honey bee toxicity of residues on foliage[9]	TEP	12
850.3040	Field testing for pollinators (Tier 3)[9]	TEP	24
850.4100	Seedling emergence (Tier 2)	TEP	12
850.4150	Vegetative vigor (Tier 2)	TEP	12
850.6100	Environmental chemistry methods/independent laboratory validations in soil, water[10]	TGAI	12
875.2100	Dislodgeable foliar residue and turf transferable residues	TEP	12
Non-guideline	Acute oral toxicity to adult honey bees (Tier 1)	TGAI	12
Non-guideline	Acute oral toxicity to larval honey bees (Tier 1)	TGAI	12
Non-guideline	Chronic oral toxicity to adult honey bees (Tier 1)	TGAI	12
Non-guideline	Chronic oral toxicity to larval honey bees (Tier 1)	TGAI	12
Non-guideline	Field trial of residues in pollen and nectar[9]	TEP	24
Non-guideline	Semi-field testing for pollinators[9]	TGAI/TEP	24
Planned Data Needs for Tebuconazole – Antimicrobial Uses Only			

[5] Algal toxicity data required on two species of non-vascular plants (freshwater and marine diatoms).
[6] In a Federal Register Notice dated June 27, 2012, EPA split the Public Draft OPPTS 850.5400 test guideline into two test guidelines: OCSPP 850.4500 and OCSPP 850.4550. See "Final Test Guidelines; OCSPP 850 Series; Notice of Availability" 77 FR 38282, June 27, 2012. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0154-0028.
[7] Chronic sediment toxicity data required on two freshwater species (an amphipod and a midge) in support of conventional uses. Only the freshwater amphipod data are required in support of antimicrobial uses.
[8] Chronic sediment toxicity data required on one species of estuarine/marine amphipod in support of both conventional and antimicrobial uses.
[9] Study may be waived depending on results of Tier 1 pollinator studies.
[10] ECM/ILV needed for soil and water.

Table 1: Planned Data Needs for the Tebuconazole Registration Review			
Guideline Number[4]	**Study Title[4]**	**Test Material**	**Estimated Timeframe (Months from receipt of DCI)**
835.1110	Activated sludge sorption isotherm[11]	TGAI	12
835.3110	Ready biodegradation[12, 13]	TGAI	12
835.3220	Porous pot[13, 14]	TGAI	12
835.3240	Simulation tests—aerobic sewage treatment: A. activated sludge[13, 15]	TGAI	12
835.3280	Simulation tests to assess the biodegradability of chemicals discharged to wastewater[13, 16]	TGAI	12
850.3300	Activated sludge respiration inhibition (ASRI) [17, 18]	TGAI	12
875.1200	Dermal Applicator Data[19]	TEP	12
875.1400	Inhalation Applicator Data[19]	TEP	12
875.1700	Product Use Data	TEP	12
875.2300	Indoor Residue Data (wipe study)[20]	TEP	12

TGAI = technical grade active ingredient; TEP = typical end-use product

[11] EPA has a published final guideline for this study: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0152-0003.

[12] EPA has a published final guideline for this study: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0152-0017. The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.

[13] The results of the Activated Sludge Respiration Inhibition Test (ASRI), GLN 850.3300, will determine which of the four biodegradation tests is/are required.

◦If the ASRI test EC50 is less than or equal to 20 mg/L, then either the (i) Biodegradation in Activated Sludge Study, GLN 835.3280 or (ii) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, GLN 835.3240, or (iii) the Porous Pot Test, GLN 835.3220 is required. If the ASRI test EC50 is greater than 20 mg/L, then the registrant must conduct either: (i) Ready Biodegradability or (ii) a) Biodegradation in Activated Sludge, or b) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, or c) the Porous Pot Test.

◦If the Ready Biodegradability study is conducted and passes, then no further testing is required. If, however, the antimicrobial fails the Ready Biodegradability study, then the (i) Biodegradation in Activated Sludge, or (ii) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, or (iii) the Porous Pot study is required.

[14] EPA has a published final guideline for this study: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0152-0024. The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.

[15] EPA has a published final guideline for this study: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0152-0034. The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.

[16] EPA has a published final guideline for this study: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0152-0036. The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.

[17] EPA published draft guidance under guideline 850.6800 and has since published final guidance for this study under guideline 850.3300: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0154-0021.

[18] OECD Test Guideline 209 can also be used as guidance for this study, available online at http://www.oecd-ilibrary.org/content/book/9789264070080-en.

[19] The following data/scenarios are needed: pressure treatment, liquid pour, sapstain, brush/roller, and airless sprayer.

[20] The wipe study is based on the need to assess dermal and incidental oral exposures to children playing on pressure treated decks and play sets.

RISK ASSESSMENTS FOR REGISTRATION REVIEW

During registration review, the Agency will conduct a comprehensive ecological risk assessment, including an endangered species assessment, for all uses of tebuconazole. For human health, EPA will conduct a revised occupational and residential post-application risk assessments for conventional uses, as well as occupational handler and residential handler and post-application risk assessments for antimicrobial uses. If toxicological endpoints or points of departure are revised based on the data that are required for registration review, they will be considered in the new assessments, as well as any changes to the standard operating procedures or default exposure assumptions.

Table 2 below summarizes the planned registration review risk assessments based on the EFED Problem Formulation and HED Scoping Document and the planned assessments have not changed from what was included in the PWP.

Table 2: Planned Risk Assessments for the Tebuconazole Registration Review		
Type of Risk Assessment	**Conduct?**	**Notes**
Ecological and Environmental Fate		
Comprehensive ecological (species to be assessed include terrestrial and aquatic organisms), including endangered species	Y	The stressor of ecological concern for terrestrial and aquatic organisms for the ecological risk assessment will only be the parent compound, tebuconazole.
Incidents	Will check for updates	For a discussion of reported ecological incidents for tebuconazole, see page 30 of the Problem Formulation.
Human Health		
Dietary		
Food	N	The dietary assessment is up to date and therefore not anticipated for registration review unless there are increases to the drinking water exposure estimates that need to be incorporated.
Drinking water	N	The dietary assessment is up to date and therefore not anticipated for registration review unless there are increases to the drinking water exposure estimates that need to be incorporated.
Occupational		
Handlers (mixers, loaders, applicators)	N	Conventional use occupational handler risk assessments are up to date and therefore not anticipated for registration review.
	Y	Antimicrobial use occupational handler risk assessments are anticipated for registration review in support of wood and material preservation uses.
Post-application	Y	A revised conventional use occupational post-application risk assessment is anticipated to address uncertainty in turf transferable residues and dislodgeable foliar residues.
	N	A revised antimicrobial occupational post-application risk assessment is not anticipated because any exposure for wood pressure treatment plants and machinists will already be captured in the occupational handler assessment.
Residential		
Handlers	N	Conventional use residential handler risk assessments are up to date and therefore not anticipated for registration review.

	Y	Antimicrobial use residential handler risk assessments are anticipated for registration review in support of the application of treated stains.
Post-application	Y	A revised conventional use residential post-application risk assessment is anticipated to address uncertainty in turf transferable residues.
	Y	A revised antimicrobial residential post-application risk assessment is anticipated to address exposure to treated wood and plastic.
Other		
Aggregate	Y	The short-term aggregate assessment will be re-evaluated when the residential assessment is updated.
Cumulative	N	There is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles.
Tolerances	N	A tolerance re-assessment is not anticipated in registration review. However, some tolerance expressions may be updated.
Incidents	Will check for updates	For a discussion of reported human incidents for tebuconazole, see page 14 of the Scoping Document and the *Tebuconazole: Tier I Review of Human Incidents.*

TIMELINE

EPA has created the following estimated timeline for the completion of the tebuconazole registration review in Table 3 below. The projected timeline has not changed since the PWP.

Table 3: Projected Tebuconazole Registration Review Timeline

Activities	Estimated Date
Opening the Docket	
Open Docket and 60-day Public Comment Period	December 2015 - Completed
Close Public Comment	February 2016 - Completed
Case Development	
Final Work Plan	June 2016 – Completed
Issue DCI	July – Sept. 2016
Data Submission	July – Sept. 2018
60-day Public Comment Period for Draft Risk Assessments[21]	January – March 2020
Registration Review Decision	

[21] The regulations governing registration review generally require the Agency to provide a public comment period of at least 30 calendar days for draft risk assessments; see 40 CFR Part 155.53(c). For conventional pesticides, the Agency plans to provide a 60 calendar day public comment period generally for draft risk assessments.

Table 3: Projected Tebuconazole Registration Review Timeline	
Activities	**Estimated Date**
60-day Public Comment Period for Proposed Registration Review Decision	October – December 2020
Registration Review Decision and Begin Post-Decision Follow-up	April – June 2021
Total (years)	6

NEXT STEPS

As noted previously, the Agency plans to require several environmental fate, ecological effects, and human health studies for tebuconazole through a Data Call-In Notice, expected to be issued in 2016.